IMPACCT

NCT05348395

IRB Approved Date: 25MAR24

Wake Forest®
School of Medicine

Division of Public Health Sciences,
Department of Epidemiology and Prevention

MECHANISM OF MONOCYTE PRIMING IN HUMANS- A FEEDING TRIAL

Informed Consent Form to Participate in Research
Jamy Ard, MD, Principal Investigator

SUMMARY

You are invited to participate in a research study. The purpose of this research is to test the effects of a typical, high-calorie Western diet on a type of white blood cell called a monocyte in healthy adults. You are invited to be in this study because you are a healthy adult. Your participation in this research will involve 2 screening visits, a baseline or "run-in" period of up to 1 month, and 8 weeks of being fed the high-calorie Western diet (experimental diet).

Participation in this study will require that you consume a diet prepared for you in our research kitchen. All research studies involve some risks. A risk to this study that you should be aware of is potential for some weight gain during the 8 weeks of the experimental diet. It is unlikely that you will benefit directly from participation in this study.

Your participation in this study is voluntary. You do not have to participate in this study if you do not want to. You will not lose any services, benefits, or rights you would normally have if you choose not to participate.

The remainder of this form contains a more complete description of this study. Please read this description carefully. You can ask any questions if you need help deciding whether to join the study. The person in charge of this study is Jamy D. Ard, MD. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his contact information is:

Jamy D. Ard, MD
[redacted]

If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact the Institutional Review Board at [redacted] or the Wake Forest University Health Sciences Research Subject Advocate at [redacted].

IRB Template Version 3/1/2022
Consent Version 4, updated 26 Feb 2024

INTRODUCTION

You are invited to be in a research study. Research studies are designed to gain scientific knowledge that may help other people in the future. You are being asked to take part in this study because you are a healthy adult. Your participation is voluntary. Please take your time in making your decision as to whether or not you wish to participate. Ask your study doctor or the study staff to explain any words or information contained in this informed consent document that you do not understand. You may also discuss the study with your friends and family.

WHY IS THIS STUDY BEING DONE?

The purpose of this research study is to understand how a high-calorie Western diet affects a type of white blood cells called monocyte. These blood cells may be important contributors to the process of how heart disease develops as a result of the types of foods we eat. Studies in animals like mice and baboons suggest that high-calorie Western diets have a bad effect on monocytes, and as a result, monocytes start a process that leads to an increase in inflammation and risk for heart disease.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

Approximately 30 people will take part in this study, all of which will participate at this research site.

WHAT IS INVOLVED IN THE STUDY?

If you agree, you will complete a screening process to determine if you are eligible to participate in the study. One major criterion to be included in this study is being able to eat the food provided in the study. The menus will include a variety of foods and ingredients that are found in a typical American diet, including grains, meat, poultry, fish/seafood, fruit, vegetables, dairy, oils/fats, nuts, seeds, and added sugar. If you have food allergies, intolerances, or special dietary needs, this study may not be for you. If you are eligible, we will stabilize your weight with the baseline diet; the baseline diet will be provided to you for up to 14 days. Once your weight is stabilized, you will switch to the experimental diet. The experimental diet will be provided to you for 8 weeks. During this time, you will have blood draws to monitor how the diet is affecting your monocytes.

At your first study visits, medical history will be collected. A physical exam and blood work will be completed. The study team will review the diet menus that you would be expected to eat during the study to understand if you have any objections to the types of food that would be provided. If you do have any concerns about the menu that cannot be resolved, then you would be ineligible to participate in the study. At the completion of the initial visit, the study team will teach you how to track your food intake and estimate how much food you have remaining after eating a meal or snack. You will be asked to practice tracking your food intake and estimating the amount of food waste for one week.

At the second study visit, you will have another chance to review the study diet. We will also

review the food diary and estimates of food waste that you completed previously. We will check your weight and blood pressure again as well. If you are eligible after this visit, we will schedule a time for you to begin the baseline diet. For female participants with a regular menstrual cycle, the start date will be based on last menstrual period (approximately 12-16 days since the end of the last period).

During the baseline diet, the goal will be to establish a stable weight for 5 days in a row. You will eat the baseline diet for 5 days and the weight on the 5th day will be the target weight to maintain. We will adjust your baseline diet to help stabilize the weight in a small range after that 5th day. Because we want to establish a stable weight for 5 days in a row, the minimum amount of time you will eat the baseline diet is 10 days. If it appears that we will not be able to stabilize your weight by day 9 of the baseline diet, you will be dismissed from the study.

During the baseline diet, you will also need to show that you can eat all of the food and beverages provided without any difficulty and track how much of the food you consumed. If you have difficulty with the foods in the diet, such as intolerances or inability to consume most of the food, you will be dismissed from the study. The baseline diet will be a diet that follows current recommendations for saturated fat (7% of calories or less) and contains a low amount of fructose (4% of calories). The number of calories you will get in the baseline diet should be enough to help you maintain your weight.

If you successfully complete the baseline diet, you will proceed to the experimental diet for the next 8 weeks. The experimental diet will differ from the baseline diet in 3 major ways. First, the experimental diet will have a higher number of calories than your baseline diet. You will get approximately 25% more calories than you had during the baseline diet. Second, you will have a higher amount of saturated fat in the experimental diet. Approximately 15% of the calories you receive will be from saturated fat. Third, you will have a higher amount of fructose in the experimental diet. Approximately 14% of the calories you receive will be from fructose.

In this study, we will provide all of the food and beverages that we want you to consume. If you participate in this study, we will expect that you limit your food and beverage intake primarily to the items we provide you. You will be able to add water and other zero-calorie beverages as needed. To get the food, you will come to the Clinical Research Unit to pick up meals 3 days per week and get the rest of your food to last until your next visit. We will also expect that you maintain a consistent level of exercise and activity throughout the study—that is we do not want you to change anything about your activity level during the study.

If you take part in this study, you will have the following tests and procedures: weight, blood pressure, labs, and physical exams. These will be conducted at the Clinical Research Unit at the start of the study. Blood will be drawn at the first screening visit, once at the end of baseline period, and weekly during the experimental diet (8 times).

Blood drawing
You will have approximately 4 teaspoons of blood withdrawn from a vein up to 10 times throughout the course of the study. The total amount of blood withdrawn during the study will be approximately 40 teaspoons (or about 13 tablespoons).

We can send copies of your test results to your personal physician. Even if you do not wish to have any of your medical information sent to your physician, you can still participate in this research study. The following tests may be performed: HbA1c, Insulin, Lipids, and Comprehensive Metabolic Panel (CMP). Results that are deemed clinically significant may be shared with your personal physician.

Do you request that we send important medical findings from your study tests/exams to your personal physician?

[ ] Yes [ ] No _____ Initials

STORAGE OF BIOLOGICAL SPECIMENS

If you agree to participate in this study, some of the samples will be kept and may be used in future research to learn more about other diseases. The sample will be stored and it will be given only to researchers approved by Dr. Ard. An Institutional Review Board (IRB) must also approve any future research study using your tissue sample. In the future, research on your specimen may involve whole genome sequencing.

The research that may be performed with your blood sample is not designed to help you specifically. There is no personal benefit to you from taking part in this aspect of the research study. The results of the research performed with your blood will not be given to you or your doctor. The results will not be put in your medical record. The research using your blood sample will not affect your care.

Your blood sample will be used only for research and will not be sold. The findings from this research may result in the future development of products that are of commercial value. There are no plans to share any of the profits with you which may occur as a result of the research.

Blood storage
Your blood sample will be stored with a unique identifier and will not include any identifiable information about you such as your name, address, telephone number, or social security number. The unique identifier will be a randomly assigned number and only the principal investigator will have access to the code that links the unique identifier to you.

As part of this research study, you will be asked to provide a biological specimen (i.e. blood, urine, saliva, etc.) to be stored and kept for future research. The future research may include studying your genetic information. At some point in the future, we may be required to share genetic data with federal repositories. The National Institutes of Health (NIH) and other central

repositories have developed special data (information) banks that collect the results of genetic studies, especially when the research looks at all or large sections of individual's genetic code. This is often called whole genome sequencing. Genomic information relates to the structure and function of all of the genetic material in the body. These central banks will store your genetic information and give them to other qualified and approved researchers to do more studies. The data that we share with federal repositories will be coded in such a way that you would not be able to be identified. We will not share your name, birth date, or any other information that could directly identify you. The link to the code would be kept securely by the researcher. Even so, there is a possibility that when your genomic information is combined with other information available to researchers, either now or in the future, they may be able to identify a group you belong to (like an ethnic group or a disease population) or, less likely, you personally. NIH prohibits people from trying to identify individuals whose genomic information is in an NIH-designated repository.

We do not think that there will be further risks to your privacy and confidentiality by sharing your genetic information with these banks. However, we cannot predict how genetic information will be used in the future. The genetic data could be used to study a wide variety of diseases.

A federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information.

This law will protect you in the following ways:
• Health insurance companies and group health plans may not request your genetic information that we get from this research.
• Health insurance companies and group health plans may not use your genetic information that we get from this research when making decisions regarding your eligibility or premiums.
• Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Be aware that this federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance, nor does it protect you against genetic discrimination by all employers.

How Long Will I Be in the Study?

You will be in the study for about 14 weeks.

You can stop participating at any time. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences.

WHAT ARE THE RISKS OF THE STUDY?

Being in this study involves some risk to you. You should discuss the risk of being in this study with the study staff. Risks and side effects related to the procedures we are studying include:

You will receive prepared meals from our Clinical Research Unit (CRU) for up to 12 weeks of intervention. You could experience foodborne illness if you improperly store or prepare the meals provided to you. The CRU staff will explain how to store and prepare your meals to minimize this risk. You might also experience an allergic reaction (such as rash or hives) to ingredients in the study-provided meals. Should you have a reaction to one of the provided meals, you should immediately stop consuming it and contact the study staff.

When starting the experimental diet, you may experience some nausea due to the increase in fructose. To help alleviate this, you will be instructed to gradually increase your caloric intake over the first 3-4 weeks of the experimental phase. The study doctor and dieticians can also counsel you on ways to reduce nausea as you begin the experimental phase.

You might experience some weight gain during the experimental diet portion of this study. We expect that you might gain 4-8 pounds during this time, although it could be slightly more. This is primarily a result of the increased number of calories that you will be fed over the 8 weeks. Because you would be expected to gain weight during the 8 weeks of experimental feeding, we will provide counseling at the completion of the trial to help participants lose weight back to baseline. The study dietitian will provide counseling to help you lose back to your initial weight. Participants will have access to counseling on a monthly basis for up to 12 months. If additional support is needed beyond this to assist with returning to a baseline weight, Dr. Ard can do an individual medical visit to come up with plans to assist with returning to the baseline weight.

In addition, there is a slight risk of a breach of confidentiality. Taking part in this research study may involve providing information that you consider confidential or private. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe.

There also may be other risks that we cannot predict. You should tell the research staff about all the medications, vitamins and supplements you take and any medical conditions you have. This may help avoid side effects, interactions and other risks.

Taking part in this research study may involve providing information that you consider confidential or private. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe.

Following blood draws, you may experience discomfort, bruising and/or bleeding where the needle is inserted. Occasionally some people become dizzy lightheaded or feel faint. Infection

may occur on rare occasions. Frequent donation of blood can result in low iron in your blood (iron deficient anemia).

Reproductive Risks and other Issues to Participating in Research

Pregnant and lactating women are excluded from participation in this study. If you are a sexually active woman of childbearing potential and have not been using a reliable method of birth control, two negative pregnancy tests performed 15 days apart are required to check for possible early pregnancy prior to starting treatment.

Are There Benefits to Taking Part in the Study?

You are not expected to receive any direct benefit from taking part in this research study. We hope the information learned from this study will benefit other people in the future.

What Other Choices Are There?

This is not a treatment study. Your alternative is to not participate in this study.

What Are the Costs?

All study costs, including any study products and procedures related directly to the study, will be paid for by the study. The food provided by the study will be at no cost to you. Costs for your regular medical care, which are not related to this study, will be your own responsibility.

Will Your Research Records be Confidential?

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed unless it is authorized by you, required by law, or necessary to protect the safety of yourself or others. There is always some risk that even de-identified information might be re-identified.

Your information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or

others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

WILL YOU BE PAID FOR PARTICIPATING?

You will be paid $150 if you complete all the scheduled study visits. If you withdraw for any reason from the study before completion you will be paid $50 for completing the baseline diet phase and $50 for completing through 4 weeks of the experimental diet phase.

WHO IS SPONSORING THIS STUDY?

This study is being sponsored by the National Institutes of Health. The sponsor is providing money or other support to Wake Forest University Health Sciences to help conduct this study. The researchers do not, however, hold a direct financial interest in the sponsor.

WHAT HAPPENS IF YOU EXPERIENCE AN INJURY OR ILLNESS AS A RESULT OF PARTICIPATING IN THIS STUDY?

Wake Forest University Baptist Medical Center maintains limited research insurance coverage for the usual and customary medical fees for reasonable and necessary treatment of injuries or illnesses to some participants in certain research studies. To the extent research insurance coverage is available under this policy, the reasonable costs of these necessary medical services will be paid, up to a maximum of $25,000. To the extent research coverage is not available, you or your insurance company may be charged for the costs of medical care. You may receive care at Wake Forest University Baptist Medical Center and/or Atrium Health.

If you are injured, the insurer may require information such as your name, social security number, and date of birth in order to pay for your care. This is because the insurer is required by law to report any payments made to cover the care of any persons who are members of a government insurance plan to the Department of Health and Human Services.

You do not give up any legal rights as a research participant by signing this consent form. For more information on medical treatment for research related injuries or to report a study related illness, adverse event, or injury you should call Jamy D. Ard, MD at [redacted] or [redacted] (after hours).

WHAT ABOUT MY HEALTH INFORMATION?

In this research study, any new information we collect from you and/or information we get from your medical records or other facilities about your health or behaviors is considered Protected Health Information. The information we will collect for this research study include demographics and medical history**.**

If this research study involves the diagnosis or treatment of a medical condition, then Protected Health Information collected from you during this study will be placed in your medical record, and may be used to help treat you, arrange payment for your care, or assist with Medical Center operations.

We will take steps to keep your Protected Health Information private. We will store records of your Protected Health Information in a cabinet in a locked office or on a password protected computer.

Your personal health information and information that identifies you ("your health information") may be given to others during and after the study. This is for reasons such as to carry out the study, to determine the results of the study, to make sure the study is being done correctly, to provide required reports and to get approval for new products.

Some of the people, agencies and businesses that may receive and use your health information are the research sponsor; representatives of the sponsor assisting with the research; investigators at other sites who are assisting with the research; central laboratories, reading centers or analysis centers; the Institutional Review Board; representatives of Wake Forest University Health Sciences and North Carolina Baptist Hospital; representatives from government agencies such as the Food and Drug Administration (FDA) or the Office of Human Research Protections (OHRP), the Department of Health and Human Services (DHHS) and similar agencies in other countries.

Some of these people, agencies and businesses may further disclose your health information. If disclosed by them, your health information may no longer be covered by federal or state privacy regulations. Your health information may be disclosed if required by law. Your health information may be used to create information that does not directly identify you. This information may be used by other researchers. You will not be directly identified in any publication or presentation that may result from this study unless there are photographs or recorded media which are identifiable.

Monitors, auditors, IRB or other regulatory agencies will be granted direct access to the participant's original medical record for verification of clinical trial procedures or data, without violating confidentiality of the participant and to the extent permitted by other applicable laws.

If required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your Protected Health Information is shared with any of these groups it may no longer be protected by federal or state

privacy rules.

Any Protected Health Information collected from you in this study that is maintained in the research records will be kept for at least six years after the study is finished. At that time any research information not already in your medical record will either be destroyed or it will be de-identified.

Any research information entered into your medical record will be kept for as long as your medical record is kept by the Medical Center. You will not be able to obtain a copy of your Protected Health Information in the research records until all activities in the study are completely finished.

You can tell Dr. Jamy Ard that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:

Jamy D. Ard, MD
[redacted]

[redacted] if you take away permission to use your Protected Health Information you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study.

By signing this form you give us permission to use your Protected Health Information for this study.

If you choose to participate in this study, your medical record at Atrium Health, Wake Forest University Health Sciences, or their respective affiliated entities will indicate that you are enrolled in a clinical trial. Information about the research and any medications or devices you are being given as a participant may also be included in your medical record. Authorization to access this part of the medical record will only be available to people who have a need to know this information in order to perform their job-related duties. If you are not a patient of these health care facilities, a medical record will be created for you anyway to provide access to this important information to providers in case of an emergency.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this Web site at any time.

Laboratory test results and other clinically relevant medical reports created as a result of your participation in the research study may be entered into the computer systems of Atrium Health, Wake Forest University Health Sciences, and/or their respective affiliated entities. These results

and reports will be kept secure in compliance with applicable laws, with permission to access this information limited to individuals with proper authority, but who may not be directly involved with this research study.

A medical record will be created for all study participants seen on-site, if a medical record doesn't already exist. Information about your participation in the study will be placed in the medical record, along with any routine medical test results that were obtained as part of this study.

What Are My Rights as a Research Study Participant?

Taking part in this study is voluntary. You may choose not to take part or you may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. The investigators also have the right to stop your participation in the study at any time. This could be because it is in your best medical interest, you had an unexpected reaction, you failed to follow instructions, or because the entire study has been stopped. Information that identifies you may be removed from the data or specimens that are collected as part of this study and could be used for future research or shared with others without additional consent.

You will be given any new information we become aware of that would affect your willingness to continue to participate in the study.

This study may be enrolling students from the Wake Forest University and/or Atrium Health and Wake Forest University School of Medicine. In addition to your rights as a research participant noted in the previous section, as a student, you are under no obligation to participate in this study. You may refuse to participate or withdraw from the study at any time and for any reason without affecting your grades, performance evaluations, or assignments. You will not be pressured into participating in this research study by any statements or implied statements that your grades, performance evaluations or assignments will be affected by your willingness to enroll in the study. Your medical records/information will not be used by the faculty, administration or study staff to make decisions regarding the status of your medical benefits. If you have questions regarding your enrollment in the study and your status as a student, please contact the research subject advocate for additional information.

Whom Do I Call if I Have Questions or Problems?

For questions about the study or in the event of a research-related injury, contact the study investigator, Dr. Jamy Ard at [redacted] or [redacted] (after hours).

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain

additional information, you should contact the Chairman of the IRB at [redacted] or the Research Subject Advocate at [redacted].

You will be given a copy of this signed consent form.

SIGNATURES

I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. If I have not already received a copy of the Privacy Notice, I may request one or one will be made available to me. I have had a chance to ask questions about being in this study and have those questions answered. By signing this consent and authorization form, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Subject Name (Printed):_____

Subject Signature: _____ Date: _____Time:_____ am pm

Person Obtaining Consent (Printed):_____

Person Obtaining Consent:_____ Date:_____ Time:_____ am pm